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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,564

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Hisashi Sakamoto

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EXAMINER

WHITE, DENNIS MICHAEL

ART UNIT

PAPER NUMBER

1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,564	Applicant(s) SAKAMOTO ET AL.	
	Examiner DENNIS M. WHITE	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04/13/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/13/2009 has been entered. Claim 1 is amended and claims 10-13 are new. Currently claims 1-13 are pending.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "wherein the at least one balance pad is formed on a rear surface of the substrate on a front face of which the at least one reagent pad is formed" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

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and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112 First Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 10-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Support for the limitation, "there is no liquid movement between the balance pad and the reagent pad" is not found in the original disclosure.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (USP 6,514,769).

Regarding claim 1-5, Lee teaches an assay device (“a sample analysis tool”) comprising: test strip 105a, (“a substrate” “strip shaped”); a test zone 112a, a control zone 113 and a determinant pad 300 (“at least one reagent pad” “two or more of the at least one reagent pad are arranged in series along a longitudinal direction of the strip shaped substrate”) (Fig. 1-2) provided on the test strip substrate, wherein at least one absorbent pad 123A is provided on the exposed region of the test strip 105a (Fig. 1-2) (“balance pad” is sufficiently broad to read on any pad; “holding portion” is sufficiently broad to read on any portion capable of being held). The absorbent pad is capable of adjusting the at least one of weight balance and friction balance of the sample analysis tool. The determinant pad 300 is provided on a first end portion of the substrate, and the absorbent pad 123A is provided on a second end portion of the test strip opposite to the first end portion at a distance from the at least one reagent pad.

Regarding the limitation: "adjusts at least one of weight balance and friction balance of the sample analysis tool so as to avoid clogging when the sample analysis

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tool is supplied by a test piece feeder to an examination location”, these claims are considered process or intended use limitations, which do not further delineate the structure of the claimed apparatus from that of the prior art. Since these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus itself. These recited process or intended use limitations are accorded no patentable weight to an apparatus. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114).

Regarding claim 6-8, Lee teaches the determination pad comprises reagents to detect the pH in urine (“a reagent for a urinalysis”) (Col. 8 lines 23-30). The color change is visually analyzed (“analyzed by an analyzer”) (col. 8 lines 14-21).

Regarding claim 9, Lee teaches the determination pad ("reagent pad") is formed on the opposite side of the test strip from the absorbent pad 123a ("balance pad is formed on a rear surface of the substrate on a front face of which the at least one reagent pad is formed").

7. Claims 1-8, 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Betts et al (USP 3,907,503).

Regarding claims 1-7, 10-13, Betts et al teach a test system for analysis of chemical constituents in a test fluid comprising:

Transparent polystyrene film cut into strips ("a substrate" "strip shape" "there is no liquid movement between the balance pad and the reagent pad" "the substrate is a single layer")

Squares of test reagent paper prepared as above were attached to one end of each strip for assays such as matrix incorporated with reagent to form a reagent block for determination of the pH, while P, G, K, BI, BL and U respectively represent reagent blocks which are specifically reactable with protein, glucose, ketones, bilirubin, occult blood and urobilinogen. ("at least one reagent pad provided on a first end portion of the substrate" "wherein two or more of the reagent pad are provided on the substrate") (col. 5 lines 25-40).

Blank squares of white paper positioned on the other end of the strip (Fig. 2 and 3 below) ("at least one balance pad provided on the second end portion substrate").

Each of the test devices numbered 1 to 15 illustrated therein comprises a strip of transparent plastic film which forms a base member 16 to one end portion of which one

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or more square paper matrices 18 is affixed ("a portion other than the holding portion serves as a reagent pad arrangement region" "at least one reagent pad is provided on a side opposite to a side of the holding portion in the reagent pad arrangement region").

The other end portion of member 16 provides a handle for the test device ("second end portion of the substrate serves as a holding portion" "balance pad is provided in the holding portion" "the at least one balance pad is provided on the same side with the reagent pad") (col. 5 lines 25-40).



Regarding the limitation: "adjusts at least one of weight balance and friction balance of the sample analysis tool so as to avoid clogging when the sample analysis tool is supplied by a test piece feeder to an examination location", these claims are considered process or intended use limitations, which do not further delineate the structure of the claimed apparatus from that of the prior art. Since these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus itself. These recited process or intended use limitations are accorded no patentable weight to an apparatus. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed

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invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114).

Regarding claim 8, Betts teach the test strips are analyzed by a test system comprising a light source for directing a light beam toward said table means, movement of said table means with said test device thereon causing said opaque area and said test reagents to be moved through positions in which they successively interrupt said light beam; light responsive code sensing means positioned to receive said light beam when not so interrupted; reaction sensing means operable responsive to reactions of said test reagents when said test reagents are respectively in interrupting relation to said light beam to provide output signals; function means connected to said code sensing means and operative to interpret the relative positions of the opaque area and the test reagents; and readout means cooperable with said function means and responsive to the output signal from said reaction sensing means ("analyzer") (Claim 7).

Response to Arguments

8. Applicant's arguments filed 4/13/2009 have been fully considered but they are not persuasive.

9. Applicants argue that Lee does not disclose a sample analysis tool in which a balance pad is positioned to adjust weight balance or friction balance of the sample analysis tool so as to avoid clogging when the sample analysis tool is supplied by a test piece feeder to an examination location. It is noted that the limitations are directed to functional language that does not further limit the claimed structure. Therefore Lee meets the claimed limitations of claim 1.

10. Applicant's arguments with respect to claims 10 and 12 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS M. WHITE whose telephone number is (571)270-3747. The examiner can normally be reached on Monday-Thursday, EST 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lyle A Alexander/
Primary Examiner, Art Unit 1797

/dmw/